NOVARTIS

# Regulatory Affairs Analyst

Job ID
REQ-10022106
Sep 20, 2024
Brazil

## Summary

The Regulatory Affairs Analyst will be responsible for contributing and supporting regulatory activities related to post-approval changes for products within the organization. This position involves ensuring compliance with regulatory requirements for changes made to approved products and collaborates with cross-functional teams to prepare and submit required documentation to HA.

## About the Role

**Major accountabilities:**

- Prepare and submit post-approval changes (CMC variations) to HA, including dossier review and strategy definition.
- Conduct regulatory evaluation of post-approval changes to assess their impact and ensure adherence to relevant guidelines and legislations.
- Collaborate with cross-functional teams to define project timelines and provide information on regulatory requirements for submissions.
- Review less complex post-approval change dossiers
- Maintain and update area databases, ensuring all information and documentation is accurate and up-to-date.
- Support in reviewing and updating labeling material and ensuring compliance with HA requirements
- Participate in meetings with minor and moderate impact at trade associations
- Provide regulatory guidance and support to cross-functional teams during the development and implementation of post-approval changes.

**Minimum Requirements:**
**Work Experience:**

- Bachelor's degree in Pharmacy or related courses.
- Prior experience working in the regulatory affairs area of Pharmaceutical Industry
- Detail-oriented and highly organized, capable of managing multiple projects simultaneously
- Excellent analytical skills with the ability to interpret and apply regulatory requirements to post-approval changes.

**Languages:**

- Advanced English language proficiency.

**You'll receive:**

Competitive salary, annual bonus, pension scheme, life insurance, 30 days annual leave, year-end recess, hybrid work model (home office 2x a week), flexible working arrangements, birthday day-off, maternity and paternity leave, subsidized dining facilities, health and dental insurance, employee recognition scheme, free parking lot (Santo Amaro and Cambe), Gympass, Space Energized for Life, gym (Santo Amaro) and virtual self-development tools.

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Division
Development
Business Unit
Innovative Medicines
Location
Brazil
Site
Santo Amaro
Company / Legal Entity
BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A
Functional Area
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Job Type
Full time
Employment Type
Regular
Shift Work
No
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## Regulatory Affairs Analyst

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